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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,171	06/18/2001	Steven M. Ruben	PZ002-P2C1	9197
22195	7590	03/04/2005	EXAMINER	
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD. ROCKVILLE, MD 20850			MARTINELL, JAMES	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary

Application No.

09/882,171

Applicant(s)

RUBEN ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 25-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 25-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1634.

Applicant's election with traverse of the requirement for restriction in the reply filed on 12/17/04 is acknowledged. The traversal is on the ground(s) that a search for a given sequence among the Groups outlined in the requirement for restriction would provide useful information. This is not found persuasive because the searches do not overlap sufficiently to obviate the need for additional searching and thus a serious search burden results for the USPTO.

The requirement is still deemed proper and is therefore made FINAL.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

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The application lacks a Brief Description of the Drawings section.

The attempt to incorporate subject matter into this application by reference to materials that are not printed publications, but identified only as Accession Numbers is improper because the materials referred to are subject to change. In addition, the source of the Accession Numbers is not given. Such improper incorporations by reference occur in at least the following locations:

- (a) page 19, line 31,
- (b) page 31, line 4,
- (c) page 61, line 5,
- (d) page 66, lines 24-26,
- (e) page 70, lines 24-26,
- (f) page 77, line 28,
- (g) page 94, lines 21-24,
- (h) page 123, line 23,
- (i) page 128, lines 24-25,
- (j) page 185, line 15,
- (k) page 196, line 15,
- (l) page 201, line 6,
- (m) page 209, line 19,
- (n) page 212, lines 4-5,
- (o) page 216, lines 30-31,
- (p) page 227, line 9, page 246, line 32 through page 247, line 1, and
- (q) Table 2, pages 522-544.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 11 and 25-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "the full-length polypeptide encoded by the HSAWF26 cDNA in ATCC Deposit No: 97903" (claims 11, 32, and 40) is vague, indefinite, and incomplete because the instant application does not define what the full-length polypeptide is.
- (b) The recitation of "polypeptide at least 95% identical to a polypeptide" (claim 40) in reference to polypeptide sequences and polypeptides referred to in deposited materials is vague and indefinite because the scope of the claim cannot be determined. For example, part (a) of the claim refers to a polypeptide comprising a 328 amino acid sequence (*i.e.*, SEQ ID NO: 483). The claim embraces a 1328 amino acid polypeptide that has as only a portion of it being the 328 amino acids of SEQ ID NO: 483 and the remainder of it (*e.g.*, another 1000 amino acids) some sequence other than and not resembling at all SEQ ID NO: 483. The claim also embraces polypeptides that are 95% identical to the 1328 amino acid polypeptide. Since the sequence of the 1000 amino acids of the embraced protein is not known, the scope of the claim is not known and cannot be known.
- (c) The recitation of "the secreted portion of the polypeptide encoded by the HSAWF26 cDNA in ATCC Deposit No: 97903" (claims 11, 32, and 40) is vague, indefinite, and incomplete because the instant application does not define the secreted portion of the polypeptide.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "polypeptide at least 95% identical to a polypeptide" (claim 40) in reference to polypeptide sequences and polypeptides referred to in deposited materials is vague and indefinite because the scope of the claim cannot be determined. For example, part (a) of the claim refers to a polypeptide comprising a 328 amino acid sequence (*i.e.*, SEQ ID NO: 483). The claim embraces a 1328 amino acid polypeptide that has as only a portion of it being the 328 amino acids of SEQ ID NO: 483 and the remainder of it (*e.g.*, another 1000 amino acids) some sequence other than and not resembling at all SEQ ID NO: 483. The claim also embraces polypeptides that are 95% identical to the 1328 amino acid polypeptide. The instant application does not provide an adequate written description of such polypeptides.

Claims 40-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides that have a defined amino acid sequence, does not reasonably provide enablement for all of the polypeptides embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The recitation of "polypeptide at least 95% identical to a polypeptide" (claim 40) in reference to polypeptide sequences and polypeptides referred to in deposited materials is vague and indefinite because the scope of the claim cannot be determined. For example, part (a) of the claim refers to a polypeptide comprising a 328 amino acid sequence (*i.e.*, SEQ ID NO: 483). The claim embraces a 1328 amino acid polypeptide that has as only a portion of it being the

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328 amino acids of SEQ ID NO: 483 and the remainder of it (*e.g.*, another 1000 amino acids) some sequence other than and not resembling at all SEQ ID NO: 483. The claim also embraces polypeptides that are 95% identical to the 1328 amino acid polypeptide.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11 and 25-47 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for the claimed polypeptides. The instant application discusses Gene No. 164 at pages 246-248. The identification of tissues is not a specific utility for the claimed polypeptides. In addition, the instant application establishes no nexus between the claimed polypeptides and any disease or condition; thus assertions as to the usefulness of the claimed polypeptides in any type of treatment or prevention are not credible or substantial.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11 and 25-47 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by de la Fuente et al (Blood 90(6), 2398 (September 15, 1997)). de la Fuente et al discloses a polypeptide that is identical to SEQ ID NO: 483. Thus, the polypeptide of de la Fuente et al is embraced by the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. Only documents such as those intended for

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use in a personal or telephone interview should be faxed to the examiner's desktop workstation. Any Official Communication to the USPTO should be faxed to (571) 273-8300.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.


OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1634

3/3/05